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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,846	10/10/2003	William Richard Heineman	0091830/0517360	2736

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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)
	10/683,846	HEINEMAN ET AL.
	Examiner	**Art Unit**
	Jacqueline DiRamio	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

The amendments to claims 1 – 4, 7, 8, and 10-12 are acknowledged.

Currently, claims 1 – 22 are pending, however, claims 13 – 22 have been withdrawn as drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The amendment to claim 1 requiring, "determining the effect the finished water has on the molecular recognition of the targeted agent by a molecular recognition element," is not effectively disclosed in the specification in such a way as to how one skilled in the art would accomplish this "determining" step. The specification effectively discloses how the natural qualities and/or additives present in finished water can interfere with the molecular recognition of the targeted agent by a molecular recognition element (see paragraphs [0020]-[0024]). However, the only disclosure of a "determining" step is brief and inadequate in specifically describing how the effect of the finished water on the molecular recognition of the targeted agent by a molecular recognition element is determined. Paragraph [0030] of the specification discloses: "*to overcome the molecular recognition problems described above, the molecular recognition element can themselves be manipulated so that they can accurately recognize the modified targeted agent. Such manipulation can occur, for example,, by determining what affect the natural qualities and/or additives in the water have on the targeted agent. The molecular recognition elements can than be constructed to identity the targeted agent in its altered state.*" Therefore, the specification discusses that a determination of the "effect" the finished water has had on the molecular recognition of the targeted agent should occur, but the process involved to accomplish this "determining" step is not explicitly stated. In order for the molecular recognition element to be manipulated or constructed in such a way that it identifies the "effected" targeted agent, the alteration or modification of the targeted agent by the finished water must be determined, but again, how this alteration or modification of the targeted agent is determined is not fully described in the specification. Thus, the amendment to the "determining" step of claim 1 is not disclosed in the specification in such a way as to enable one skilled in the art to use Applicant's recited method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite the method step of: "determining the effect the finished water has on the molecular recognition of the targeted agent by a molecular recognition element," which is vague and indefinite because it is unclear what the determining step encompasses. The specification discloses the factors that can effect the molecular recognition of the targeted agent, i.e. pH, additives, metal ions, etc. (see paragraphs [0020]-[0024]). However, the only disclosure of a determining step merely discusses the manipulation of the molecular recognition elements in order to overcome the molecular recognition problems that can occur through the processes utilized to produce finished water (see paragraph [0030]). Therefore, the amended limitation, requiring "determining the effect the finished water has on the molecular recognition of the targeted agent by a molecular recognition element," is unclear, as well as vague and indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pyle et al (US 5,821,066) in view of Fritsch et al. (US 2003/0108922).

Pyle et al. teach a simple, rapid method for detection of specific microorganisms, particularly in potable water sources and water storage areas (see column 6, lines 48-53). The method comprises the steps of:

analyzing a sample for a particular target species in food or water;

determining if the target species is viable in the food or water sample, by collecting the sample and dyeing with a fluorochrome dye in order to determine the presence of any viable target cells;

selecting and providing an antibody (first molecular recognition element) that specifically binds to a particular species of target bacteria in the sample of water;

mixing (flowing) the liquid (sample) suspected to contain the target bacteria with the specific antibody (first recognition element);

capturing the bacteria (biological agent) present in the sample with the specific antibody (first recognition element) through binding;

emitting a fluorescence signal, which indicates the presence of the target bacteria in the sample (see column 7, lines 17-36; example 3, columns 17-18, and claim 1 in particular).

However, Pyle et al., which teach the method of detecting in potable water sources, fail to teach that the method also encompasses “finished water” samples.

Fritsch et al. teach an electrochemical detection method for pathogens and toxins in water supplies, particularly finished water. The method of Fritsch et al. comprises:

analyzing a sample suspected of having a target analyte (biological agent);

selecting and providing a primary analyte binding material (first molecular recognition element), which targets the biological agent in the sample;

introducing (flowing) the sample to be tested for a specific analyte to the assay structure, which contains the primary analyte binding material (first molecular recognition element);

capturing the biological analyte in the sample through binding to the primary analyte binding material (first molecular recognition element); and

creating a current (emitting a signal) within the assay structure via a electrochemically active material, which indicates the presence of the analyte in the sample (see paragraphs [0024], [0025], [0027], [0036] and [0038] in particular). By detecting the concentration of target analytes, such as toxins and pathogens, in finished water samples, the possibility of an outbreak occurring in the finished water supplies can be reduced, which provides for cleaner, safer drinking water and will reduce fatality rates worldwide (see paragraphs [0027] and [0058]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the detection method of Pyle et al. the use of finished water samples as taught by Fritsch et al. because Fritsch et al. teach the benefit of detecting pathogens in finished water samples in order to reduce the possibility of an outbreak occurring in the finished water supplies, which provides for cleaner, safer drinking water and will reduce fatality rates worldwide.

With respect to Applicant's claims 2 – 4, Pyle et al. teach that the bacteria that has been captured by binding with the specific antibody is next treated with a specific fluorescent conjugated antibody (second molecular recognition element) that also binds to the captured bacteria (see column 18, lines 2-10 in particular). The fluorescent label provides the emitted fluorescence signal to indicate the presence of the target bacteria in the sample, wherein the signal is quantifiable using an image analysis system (see column 18, lines 30-42 in particular).

With respect to Applicant's claim 5, Pyle et al. fail to teach the use of electrochemical detection, however, the method of Fritsch et al. utilizes electrochemical detection, wherein the signal emission generated through a created current is detected electrochemically (see paragraphs [0024] and [0025]). Fritsch et al. teach that their detection method can use fluorescence techniques, however, the methods of electrochemical detection provide a more accurate and less time intensive detection method (see paragraph [0049]). Therefore, it would have been obvious to include the electrochemical detection method with the method of Pyle et al. because Fritsch et al.

teach the benefit of this detection method in order to provide a more accurate and less time intensive detection method.

With respect to Applicant's claim 6, Pyle et al. teach that the signal emission is capable of fluorescence detection, as discussed above (see column 18, lines 1-42).

With respect to Applicant's claim 7, the element used by Pyle et al. to specifically bind to the target bacteria is an antibody (see column 17, lines 53-58 in particular).

With respect to Applicant's claims 8 and 9, Fritsch et al. teach the sample is treated with an electrochemically active material, which contains an electrolabeling material and either a metal ion, a redox enzyme, a metalloprotein, or a chelating agent. The electrochemically active material is added along with the secondary analyte binding material (second molecular recognition element) to bind to the target agent and create the electrochemical signal, without interfering with the primary analyte binding material (first molecular recognition element) (see Figure 1, paragraph [0063], and claim 2 in particular).

With respect to Applicant's claim 10, Pyle et al. teach the biological agents detected by the method of Pyle et al. mainly consist of pathogenic bacteria (see column 16, lines 54-56 and column 17, lines 53-56 in particular).

With respect to Applicant's claims 11 and 12, Pyle et al. teach the antibody (first molecular recognition element) used to specifically bind to the target bacteria is coated on a solid phase, particularly immunomagnetic beads (see column 17, lines 53-58 and column 18, lines 55-60).

Response to Arguments

Applicant's arguments filed September 13, 2006 have been fully considered but they are not persuasive. Applicant argues that the amendment to claim 1, requiring the step of "determining the effect said finished water has on the molecular recognition of the targeted agent by a molecular recognition element," is not taught or suggested by the applied references of Pyle et al. (US 5,821,066) or Fritsch et al. (US 2003/0108922) (see p5-8). However, the amendment to claim 1 with respect to the "determining" step is vague and indefinite because neither the claim nor the specification explicitly state how this determining step is accomplished. Therefore, the dyeing procedure of Pyle et al., wherein the target species is dyed with a fluorochrome dye in order to determine if viable cells are present in the sample, does in fact encompass the determining step of Applicant's amended claim 1. By first dyeing the sample with a fluorochrome dye, the presence of viable/respiring cells within the sample is determined, which in turn determines if the water or food sample that has gone through a treatment and/or storage process has eliminated various microbial cells. The dyed sample is then exposed to an antibody or binding agent that binds specifically to a target species, particularly a target infectious agent, in order to determine if that target species is in fact present within the sample. Further, if the target species is present in the sample and dyed by the fluorochrome dye, but not bound by the specific antibody or binding agent, it can also be determined if the treatment and/or storage process that the sample has undergone has affected the "molecular recognition" of the target species (see column 6, lines 3-54; column 7, lines 17-37; column 9, lines 46-67; column 10, lines 1-36; column

14, lines 21-53; column 18, lines 18-20; column 19, lines 32-51; column 20, lines 45-62; and column 21, lines 27-36). Thus, the applied reference of Pyle et al. does in fact teach the "determining step" of Applicant's claim 1 through the step of dyeing the sample for viable or respiring cells.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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